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Nos. 96-562 and 96-575

Supreme Court, U.S.
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In the Supreme Court of the United States

OCTOBER TERM, 1996

ORGANON, INC., PETITIONER

v.

DAVID A. KESSLER,
COMMISSIONER OF FOOD AND DRUGS, ET AL.

BRACCO DIAGNOSTICS INC. AND
BRACCO INTERNATIONAL B.V., PETITIONERS

v.

DAVID A. KESSLER,
COMMISSIONER OF FOOD AND DRUGS, ET AL.

ON PETITIONS FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF FOR THE FEDERAL RESPONDENTS IN OPPOSITION

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QUESTIONS PRESENTED

The 1994 Uruguay Round Agreements Act (URAA) establishes a new patent term of 20 years from the date on which the patent application was filed. 35 U.S.C. 154(a)(2). The transitional provision of the URAA provides that "[t]he term of a patent that is in force on or that results from an application filed before [June 8, 1995] shall be the greater of the 20-year term as provided in subsection (a) or 17 years from grant, subject to any terminal disclaimers." 35 U.S.C. 154(c)(1).

1. The petitions in Nos. 96-562 and 96-575 present the question whether the requirement of the Hatch-Waxman Act, 35 U.S.C. 156(a)(2), that, in order to receive a Hatch-Waxman Act extension, a patent must not have been previously extended under Section 156(e)(1) of that Act, precludes adding such extension to the URAA's new 20-year term for patents that were in force on the effective date of the URAA solely because the patent's original 17-year term had been extended pursuant to Section 156(e)(1).

2. An additional question presented by the petition in No. 96-562 is whether the Food and Drug Administration (FDA) violated the Administrative Procedure Act (APA), 5 U.S.C. 553, by publishing a notice, without prior notice and comment, stating that FDA would not publish patent expiration dates submitted by applicants for new drug applications and new animal drug applications if the submitter stated that the expiration dates were not calculated in accordance with the Patent and Trademark Office's (PTO) Final Determination regarding whether an extension under the Hatch-Waxman Act could be added to the URAA's newly created 20-year patent term.

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OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a-23a)[1] is reported at 80 F.3d 1543. The opinion of the

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[1] Unless otherwise indicated, Pet. App. refers to the Appendix in No. 96-562.

district court in No. 96-575 (Pet. App. 28a-39a) is reported at 903 F. Supp. 964. The opinion of the district court in No. 96-562 (Pet. App. 24a-27a) is unreported. The district court's orders on remand from the court of appeals' decision (Pet. App. 40a-41a; 96-575 Pet. App. 29a-34a) are unreported.

JURISDICTION

The judgment of the court of appeals (Pet. App. 92a-94a) was entered on April 4, 1996, and its mandate was issued on July 19, 1996. Petitions for rehearing were denied on July 12, 1996. Pet. App. 80a-91a. The petition for a writ of certiorari in No. 96-562 was filed on October 9, 1996, and the petition for a writ of certiorari in No. 96-575 was filed on October 10, 1996. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATEMENT

1. Prior to the enactment of the Hatch-Waxman Act and the URAA, a patent for an innovator or pioneer drug was in force for a term of 17 years from the date that the patent was issued. 35 U.S.C. 154 (1988). In 1984, Congress enacted the Hatch-Waxman Act, which incorporates the patent status of a drug, or the use of a drug, into the drug approval process, and permits certain drug patents to be extended (or restored) "from the original expiration date of the patent." 35 U.S.C. 156(a). The Section 156 extension restores some of the time spent obtaining the required pre-marketing approval from the Food and Drug Administration (FDA). See 35 U.S.C. 156(c) and (g); H.R. Rep. No. 857, 98th Cong., 2d Sess. Pt. 1, 40-41 (1984). The length of the extension varies according to several factors, but if the patent was issued and human testing began before enactment of

the Hatch-Waxman Act in 1984, the total extension may not exceed two years; otherwise the restoration period generally is limited to five years. 35 U.S.C. 156; Pet. App. 4a-5a. The extension may be granted only if the patent has not been extended under Section 156(e)(1). 35 U.S.C. 156(a)(2). In addition, the extension may not extend the effective life of the patent more than 14 years following FDA approval of the New Drug Application (NDA). 35 U.S.C. 156(c)(3).

2. Effective June 8, 1995, the URAA establishes a new patent term of 20 years from the date on which the application for the patent was filed. 35 U.S.C. 154(a)(2). The transitional provision of the URAA states that "[t]he term of a patent that is in force on or that results from an application filed before [June 8, 1995] shall be the greater of the 20-year term as provided in [the URAA] or 17 years from grant, subject to any terminal disclaimers." 35 U.S.C. 154(c)(1). The URAA does not address how Hatch-Waxman extensions under Section 156 are to be applied during the transition period.

After notice and comment, PTO published on June 7, 1995, its "Final Determination" to resolve how it would apply Section 156 extensions to patents covered by Section 154's transitional provision. Pet. App. 56a-66a. Relying on the statutory language of the Hatch-Waxman Act that provides that the extension runs "from the original expiration date of the patent," 35 U.S.C. 156(a), PTO determined that with respect to patents that were in force on or resulted from applications filed before June 8, 1995, Hatch-Waxman extensions could be added only to the original term of 17 years from the date of the patent's issuance, not the new 20-year term. Thus, under PTO's ruling, holders of patents of innovator or pioneer drugs covered by

the transitional provision of the URAA, 35 U.S.C. 154(c)(1), were entitled to the greater of the 17-year term plus the Hatch-Waxman extension, or a term of 20 years from the date the patent application was filed.

3. Companies seeking to market pioneer or innovator drugs must first obtain FDA approval through the filing of a New Drug Application. 21 U.S.C. 355. In addition to submitting to FDA data that demonstrate the safety and effectiveness of the drug, the Hatch-Waxman Act requires applicants to provide the FDA with "the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." 21 U.S.C. 355(b)(1). FDA publishes this information in its *Approved Drug Products With Therapeutic Equivalence Evaluations* (commonly known as the "Orange Book"). 21 C.F.R. 314.53(e).

A manufacturer who wishes to market a generic version of a pioneer drug must submit to FDA an Abbreviated New Drug Application (ANDA). 21 U.S.C. 355(a) and (j). The ANDA must contain, among other things, a certification with respect to each patent that claims the drug or method of the drug's use. 21 U.S.C. 355(j)(2)(A)(vii).[2] A certifica-

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[2] The certification must state one of the following:

(I) that such patent information has not been filed,

(II) that such patent has expired,

(III) * * * the date on which such patent will expire, or

tion that the applicable patent is invalid or will not be infringed (see note 2, *supra*) requires that the ANDA applicant give notice of the ANDA filing to the patent owner and the NDA holder for the listed drug.[3] FDA may approve an ANDA with such a certification, effective immediately, despite the unexpired patent, unless an action for infringement is brought against the ANDA applicant within 45 days of receipt of the certification. 21 U.S.C. 355(j)(4)(B)(iii). If an infringement action is brought, approval of the ANDA will not become effective until 30 months from receipt of the certification notice, unless the infringement case is decided sooner or the court shortens or extends the period. 21 U.S.C. 355(j)(4)(B)(iii).

On June 8, 1995, FDA issued a notice which, while not stating a position on the patent law question involved in this case, required that NDA holders submit new patent term expiration dates if the patent term was affected by the URAA. Pet. App. 67a-73a. FDA also requested that ANDA applicants amend any pending applications to respond to any URAA-affected dates submitted by NDA holders. *Id.* at 71a-72a. In response to this notice, FDA received a number of submissions that stated that the patent expiration dates were not calculated in accordance with PTO's Final Determination, but instead were

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> (IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted.

21 U.S.C. 355(j)(2)(A)(vii).

[3] This notice must include a detailed statement of the factual and legal basis for the ANDA applicant's opinion that the patent is not valid or will not be infringed. 21 U.S.C. 355(j)(2)(B).

calculated by adding the Hatch-Waxman extension period to the 20-year term created by the URAA. *Id.* at 76a-77a. On July 21, 1995, FDA published a notice stating that it would not publish patent expiration dates which the submitter stated were not calculated in accordance with PTO's Final Determination. *Id.* at 74a-79a.[4] Accordingly, FDA refused to publish the holders' newly calculated expiration dates.

4. Holders of patents for pioneer or innovator drugs in force on June 8, 1995 brought suits challenging the actions of PTO and FDA. Four cases, including that of the petitioner in No. 96-575, were consolidated by order of the district court. C.A. App. 8-11.[5] The district court held that holders of patents in force on the effective date of the URAA were entitled to have the Hatch-Waxman extension period added to the URAA's newly created 20-year term. Pet. App. 28a-39a. The court declined to defer to PTO's Final

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[4] The notice also requested submission of amended patent expiration dates within 30 days of the notice. Pet. App. 74a-75a, 77a. The notice further stated that FDA would publish dates that were not expressly identified by the submitter as inconsistent with PTO's determination, and would rely on the challenge procedures of 21 C.F.R. 314.53(f) to identify incorrectly calculated dates. Pet. App. 74a, 77a. In the event of a challenge, FDA would forward the challenge to the NDA applicant and request confirmation that the expiration dates were calculated in accordance with PTO's determination. The notice also stated that, if the applicant submitting the challenged information did not submit a confirmation or corrected date, FDA would not publish the challenged date. *Id.* at 77a-78a.

[5] Those four cases are *Merck & Co., Inc., et al.* v. *Kessler, et al.*, No. 95-1005-A; *Schering Corp.* v. *Kessler, et al.*, No. 95-1052-A; *Bracco Diagnostics Inc., et al.* v. *Lehman*, No. 95-1103-A; *Hoffmann-LaRoche Inc., et al.* v. *Lehman*, No. 95-1236-A (E.D. Va.).

Determination in a "straightforward matter of statutory interpretation." *Id.* at 34a. The court noted that it was undisputed that "any patent applied for after June 8, 1995, would be for twenty years and would have the benefit of any extension available to it under 35 U.S.C. § 156." *Id.* at 32a. The court concluded that URAA's transition provision did not indicate a congressional intent to differentiate between those post-June 8, 1995 patents and patents covered by Section 154's transitional provision. Pet. App. 32a-33a. Accordingly, the court granted plaintiffs' motion for summary judgment, and entered an order (1) declaring PTO's Final Determination "invalid and unenforceable"; (2) declaring the expiration dates of the 11 patents at issue to be the dates submitted by the patent holders, *i.e.*, the URAA's 20-year period plus the Hatch-Waxman restoration period; (3) requiring FDA to publish those expiration dates in the Orange Book; and (4) prohibiting FDA from approving any applications that did not take into account the expiration dates required by the court's order. Pet. App. 38a-39a.

Less than a month after its decision in the four consolidated cases, the district court entered a memorandum opinion and order that granted petitioner in No. 96-562 "the same injunctive and declaratory relief" accorded to plaintiffs in the consolidated cases "for the same reasons set forth" in those consolidated cases. Pet. App. 24a.

5. The federal defendants appealed the four consolidated cases and petitioner Organon's case, all of which were consolidated on appeal. The court of appeals affirmed in part and reversed in part. Pet. App. 1a-23a.

The court decided the statutory interpretation question *de novo*, refusing to accord deference to PTO's Final Determination because PTO did not have substantive rulemaking authority. Pet. App. 12a-14a.[6] Further, the court rejected PTO's construction of the statutory phrase "original expiration date" in Section 156 as describing the expiration date of the original 17-year term that the patent received upon issuance, and, accordingly, PTO's conclusion that a Hatch-Waxman extension under Section 156 could be added only to the expiration of the original term of 17 years from issuance. Pet. App. 15a-16a. Instead, the court reasoned that the phrase "'original expiration date' means no more than that the expiration date has not been extended under section 156(e)(1) and, thus, the phrase can identify more than one date." *Id.* at 17a. The court determined that, for most patents covered by the URAA's transitional provision, the Hatch-Waxman extension would be added to the newly created 20-year-from-application term, if that result yielded a greater term than adding the extension to the previously existing 17-year-from-issuance term. *Id.* at 14a-20a.

The court concluded, however, that the Hatch-Waxman Act precluded the addition of the Hatch-Waxman extension to the URAA's newly created 20-year term for petitioners' patents. Pet. App. 20a-23a. Because petitioners' patents would have expired prior to the effective date of the URAA but for the fact that they were extended under Section 156, the court concluded

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[6] Because of the court's failure to give deference to PTO's interpretation of Sections 154 and 156, the federal parties have filed a conditional cross-petition simultaneously with the filing of this opposition.

that adding a Section 156 extension to the new 20-year term would constitute a second extension under Section 156 and would exceed the statutory limits of Section 156. Pet. App. 23a.

Petitioners and the federal parties filed petitions for rehearing, which the court of appeals denied. Pet. App. 80a-91a.

ARGUMENT

This case does not present an issue of public importance warranting review by this Court.

1. The statutory provision at issue is a transitional provision of only a temporally limited significance. Under the theory advanced by petitioners, the term of the patent in No. 96-562 expired on November 6, 1996 (Pet. App. 24a), a fact that appears to render that case moot.[7] The term of the patent in No. 96-575 expires on November 24, 1997. 96-575 Pet. 4. We also are informed that, to PTO's knowledge, a maximum of 41 patents, including petitioners' patents, were in force on the effective date of the URAA solely because they were extended under Section 156. Petitioners argue only that the decision of the court of appeals is wrongly decided. They suggest no reason—and we know of none—why this case involves an issue of substantial and continuing importance to the public warranting this Court's review. See *Rice* v. *Sioux City Memorial Park Cemetery*, 349 U.S. 70,

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[7] To our knowledge, no drug was approved for marketing by the FDA during the period of the patent that could result in an infringement suit. Petitioner in No. 96-562 has not suggested any other situation that would present a live controversy.

79 (1955); *Layne & Bowler Corp.* v. *Western Well Works, Inc.*, 261 U.S. 387, 393 (1923).[8]

2. In addition, the patent law arguments presented by petitioners lack merit.[9] Petitioners argue (96-562 Pet. 8-9; 96-575 Pet. 8-16) that the court of appeals' decision deprives their patents of the mandatory benefit of the 20-year term provided by the transitional provision of the URAA, 35 U.S.C. 154(c)(1). That is not correct. Petitioners' patents unquestionably receive the greater of the URAA's newly created 20-year-from-application term or their original 17-year-from-issuance term. The question presented, however, is whether transitional patents are entitled to a Hatch-Waxman extension in addition to the URAA's 20-year term when a Hatch-Waxman extension had already been granted to the patent and had at least partially expired before the effective date of the URAA. The statutory provisions at issue do not expressly answer that question. Contrary to petitioners' argument, the court of appeals correctly ruled that the provision of the Hatch-Waxman Act, 35

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[8] Although petitioners suggest (96-562 Pet. 5-6; 96-575 Pet. 6-8) that the court of appeals' decision has international ramifications, neither petition provides substantiation for that suggestion, which is implausible in light of the temporary nature of the questions presented.

[9] As we explain in our conditional cross-petition filed simultaneously with this response, PTO correctly construed Sections 154 and 156 in concluding that *none* of the patents at issue was entitled to have Section 156 extensions added to the URAA's newly created 20-year term. The court of appeals erred in not deferring to PTO's Final Determination that the term for patents in force on the URAA's effective date is the greater of the 17-year term that was originally issued to the patent, plus any applicable Hatch-Waxman extension, or the URAA's newly created term of 20 years from application.

U.S.C. 156(a)(2), that bars the grant of a Section 156 extension if the patent has previously been extended under Section 156(e)(1) of the Act, precludes the addition of a Section 156 extension onto the URAA's 20-year term for patents in force on June 8, 1995 solely because they were extended under Section 156 beyond their original 17-year term.

Section 156 provides that a Hatch-Waxman Act extension "shall be extended in accordance with this section from the original expiration date of the patent if * * * the term of the patent has never been extended under subsection (e)(1) of this section." 35 U.S.C. 156(a)(2). Petitioners seek to avoid Section 156(a)(2)'s bar against two extensions by arguing that shifting the extension from the end of the original 17-year term to the end of the URAA's new 20-year term does not constitute a second Hatch-Waxman extension. 96-562 Pet. 10-12. That argument, however, ignores the fact that petitioners' patents had received a Hatch-Waxman extension under Section 156(e)(1) and that those patents would have expired before June 8, 1995 had they not received that extension. Pet. App. 20a-21a; 96-575 Pet. 4; 96-562 Pet. 3-5.

Moreover, the result urged by petitioners belies the claim that shifting the extension from the end of the 17-year term to the end of the URAA's newly created 20-year term does not constitute a prohibited second extension. For example, the 17-year term for U.S. Patent No. 4,001,323 in No. 96-575 expired on January 4, 1994. On December 19, 1986, the patent received a two-year restoration under Section 156, which extended the patent's expiration date to January 4, 1996. Thus, the patent term used approximately 17 months of the extension prior to the effective date of the URAA. Pet. App. 21a. Under petitioners' theory,

however, the patent is entitled to an additional two-year extension at the end of the URAA's 20-year term in addition to the 17 months' extension already spent. Thus, the court of appeals correctly concluded that under petitioners' theory, the patent's "restoration extension totals 41 months, which exceeds the statutory limit of 24 months." *Ibid.*; see 35 U.S.C. 156(g)(6)(C).[10]

Similarly, the 17-year term for the patent in No. 96-562 expired on December 12, 1992. On December 11, 1992, that patent received a Section 156 extension of 1,069 days, extending the life of the patent to November 19, 1995. C.A. App. 401. Thus, the patent used approximately 890 days of the Section 156 extension prior to the URAA's effective date. Petitioner Organon nonetheless argues that its patent is entitled to have 1,069 days added to the URAA's 20-year term. That reasoning would extend petitioner's patent 1,959 days—890 days used prior to the effective date of the URAA plus 1,069 days at the end of the URAA's 20-year term. There is no support in the

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[10] The above illustration also counters the argument that "[a]pplying the restoration extension to the new 20-year term would not constitute a second extension to 'the term of the patent' as defined in Section 154(c) since the 20-year term had not previously been extended." 96-575 Pet. 14. A similar argument is made that "[t]he URAA * * * recalculated pre-June 8, 1995 patent terms for all purposes under the statutory scheme," including Section 156. 96-575 Pet. 12. Neither of those contentions, however, disputes the fact that the patents at issue, which would have expired before the effective date of the URAA but for their Section 156 extensions, are seeking the benefit of another Section 156 extension.

language of Section 156 or its underlying purpose for that result.[11]

Petitioners also argue that the court of appeals' opinion is "internally inconsistent" because the court interpreted the phrase "original expiration date" in Section 154 with reference to the new 20-year term, but held that, for petitioners' patents, "the former 17-year term of patent remained in effect for purposes of Section 156." 96-575 Pet. 13-14. That the court interpreted different terms in different statutory provisions, however, does not make the court's decision inconsistent. Moreover, as set forth in our conditional cross-petition, we believe that the court of appeals did not correctly interpret the phrase "original expiration date" in Section 154 because that phrase applies only to the original 17-year term granted to a patent when it was issued. However, even if, as we believe, the court of appeals' explanation is not entirely satisfactory, the remedy is not to add Hatch-Waxman extensions to the end of the URAA's 20-year term for all transitional patents. That result would be even more at odds with Section 156(a)'s requirement that extensions run "from the original

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[11] Petitioners also argue (96-562 Pet. 12; 96-575 Pet. 13-14) that the court of appeals' decision improperly differentiates between their patents and patents that on the effective date of the URAA had received, but not used, their extensions under Section 156. Although our position is that the bar against second extensions precludes the addition of an extension to the URAA's 20-year term for both classes of patents, the court of appeals rationally distinguished between petitioners' patents and those patents that had not used any of their Section 156 extension, because Section 156(a)(2)'s bar against second extensions more clearly applies to petitioners' patents.

expiration date of the patent" than the statutory construction adopted by the court of appeals.

3. a. Petitioner Organon argues (96-562 Pet. 12-20) that FDA's July 21, 1995 notice was not promulgated in compliance with the notice and comment requirements of the Administrative Procedure Act, 5 U.S.C. 553.[12] In that notice, FDA stated that it would not publish patent expiration dates submitted by applicants for new drug applications and new animal drug applications if the submitter stated that the expiration dates were not calculated in accordance with PTO's Final Determination. Pet. App. 74a-79a. Because the court of appeals has decided the merits of the patent law issue, the legality of FDA's notice has no continuing importance. Once the patent law issue is authoritatively resolved—whether by the court of appeals or by this Court—the FDA's decision regarding whether or not to publish expiration dates calculated in accordance with PTO's Final Determination has necessarily been superseded. Upon judicial resolution of the patent law issue, applicants for patent extensions will calculate expiration dates consistent with that resolution, and FDA will publish those dates.

b. In any event, petitioner's argument that FDA's notice is invalid because it was not promulgated in accord with the APA is misplaced. Contrary to petitioner's contention (96-562 Pet. 15-17), the notice does not constitute a new rule regarding FDA's role in publishing patent term extension dates. Absent a judicial determination to the contrary, FDA reasonably

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[12] That argument is advanced only by petitioner in No. 96-562, whose patent has expired under any construction of Sections 154 and 156. See page 9 and note 7, *supra*.

looked to PTO's Final Determination as a statement of the controlling law on the question at issue and announced that it would "not publish any patent expiration date that the submitter states is not consistent with the PTO's determination." Pet. App. 77a. That position is fully consistent with FDA's role under its regulations (21 C.F.R. 314.53(e)) and does not constitute a new rule.[13]

For similar reasons, petitioner is mistaken in arguing that the Notice constitutes a new rule regarding the procedure for challenging patent term expiration dates. 96-562 Pet. 17-18. Under 21 C.F.R. 314.53(f), the FDA does not change patent information unless the holder withdraws or amends its patent information in response to FDA's request for confirmation of the information. However, that rule does not extend to the unique circumstances present here in which the dates submitted by the transitional patent holders were expressly calculated contrary to PTO's Final Determination concerning the issue.

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[13] Petitioner also argues (96-562 Pet. 19-20) that FDA's notice promulgated a new rule interpreting the effect of the URAA on the Hatch-Waxman Act. As explained above, however, the notice simply relies on PTO's determination regarding the pertinent patent law issues, and is consistent with FDA's position that it does not make independent patent determinations.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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NOVEMBER 1996